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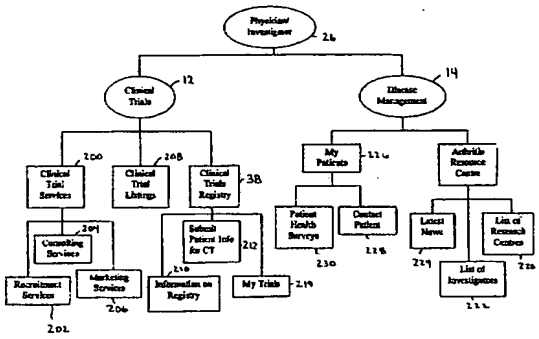
(54) METHODE ET SYSTEME DE FACILITATION DU RECRUTEMENT EN VUE D'ESSAIS CLINIQUES AINSI QUE DE LA GESTION ET DE LA SURVEILLANCE THERAPEUTIQUE

(54) METHOD AND SYSTEM FOR FACILITATING CLINICAL TRIAL RECRUITMENT AND FOR DISEASE MANAGEMENT AND SURVEILLANCE

(57)

A system and method of facilitating the determination of candidates eligible for a clinical trial includes maintaining an electronic patient registry including patient information relating to a plurality of individuals. When individuals are needed for a clinical trial, the patient registry is searched based on criteria established for the clinical trial thereby to determine potential candidates within the patient registry that are eligible for the clinical trial. Individuals can register with the electronic registry on-line. A system and method for disease management and surveillance is also provided.



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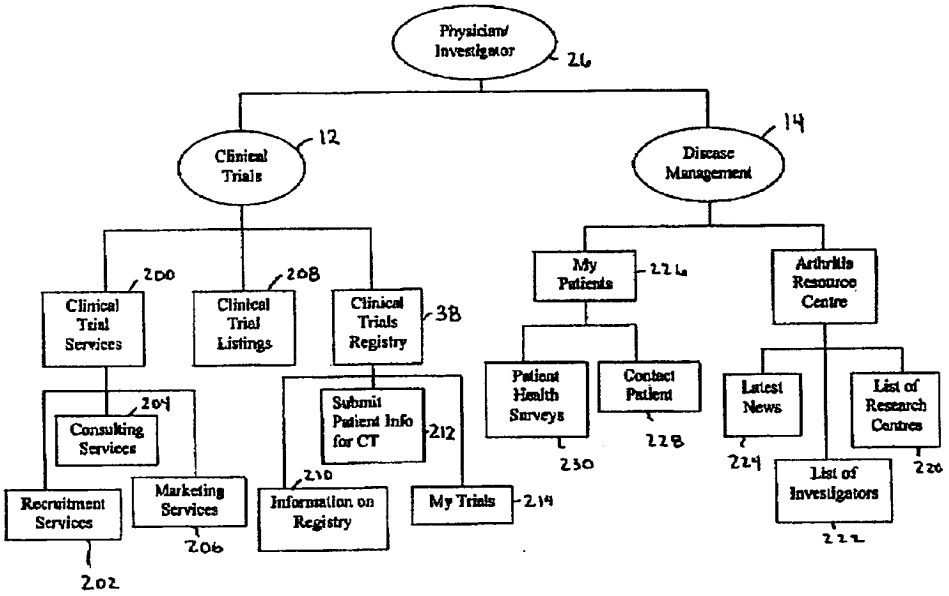


(57) Abrégé/Abstract:
A system and method of facilitating the determination of candidates eligible for a clinical trial includes maintaining an electronic patient registry including patient information relating to a plurality of individuals. When individuals are needed for a clinical trial, the patient registry is searched based on criteria established for the clinical trial thereby to determine potential candidates within the patient registry that are eligible for the clinical trial. Individuals can register with the electronic registry on-line. A system and method for disease management and surveillance is also provided.

ABSTRACT

A system and method of facilitating the determination of candidates eligible for a clinical trial includes maintaining an electronic patient registry including patient information relating to a plurality of individuals. When individuals are needed for a clinical trial, the patient registry is searched based on criteria established for the clinical trial thereby to determine potential candidates within the patient registry that are eligible for the clinical trial. Individuals can register with the electronic registry on-line. A system and method for disease management and surveillance is also provided.

SYSTEM AND METHOD OF FACILITATING CLINICAL TRIAL RECRUITMENT AND FOR DISEASE MANAGEMENT AND SURVEILLIANCE

Field Of The Invention

The present invention relates to a system and method of facilitating the determination of candidates eligible for a clinical trial. The present invention also relates to a system and method for disease management and surveillance.

Background Of The Invention

Clinical trials are one of the final stages in long processes aimed at improved disease therapy. Each clinical trial is designed to answer specific scientific questions and so it is important that the candidates participating in the clinical trial reflect the target population. Preferably, each clinical trial is randomized to reduce bias and increase the ability to generalise the results. There are different types of clinical trials (i.e. treatment trials, prevention trials, screening trials and quality of life trials) and different phases of clinical trials (i.e. Phase I (safety), Phase II (safety and efficacy), Phase III (efficacy and comparison) and Phase IV (post-approval marketing). As such, different types of candidates are needed for the different types and phases of clinical trials.

Studies are done on candidates who either volunteer or are paid to take part in a clinical trial to determine the suitability of the candidates for the clinical trial. The screening of candidates that are potential subjects is a cumbersome and time-consuming process. Rapid accrual of candidates into clinical trials requires extraordinary access to patients and patient data. Access to patients and their data has in the past been limited. This of course has presented difficulties enrolling the necessary number of suitable candidates for clinical trials. The end result has simply lengthened the time required to complete clinical trials. This of course translates directly into an increase in the time to first patient metric for patients in the clinical trials.

In an attempt to alleviate this problem, commercial and non-profit enterprises have been established to assist in the recruitment of patients for clinical trials. For example, the Canadian HIV Trials Network is a non-profit Canadian organization dedicated to supporting clinical trials involving people with HIV/AIDS. The Canadian HIV Trials Network maintains a database that lists national clinical trials. The database is accessible to individuals on-line.

The National Cancer Institute's Physician Data Query (PDQ) is a non-profit American organization dedicated to supporting clinical trials involving people with cancer. PDQ maintains a database that provides a comprehensive list of clinical trials being conducted in the United States.

Commercial enterprises that have been established to assist in the recruitment of patients for clinical trials include general clinical trial management and marketing companies, on-line clinical trial service sites and on-line general medical information sites. Examples of general clinical trial management and marketing companies include Quintiles, Rheumatology Research International and Healthcare Communications Group.

The on-line clinical trial service sites are primarily focused on clinical trials and generate revenues from drug development companies for on-line marketing and recruitment. Examples of these on-line clinical trial service sites include Centerwatch, The Health Exchange and Medistudy.

The on-line general medical information sites offer listings and/or active recruitment of patients for clinical trials. Examples of these on-line general medical information sites include DrKoop and AmericasDoctor.

In addition to the above-described enterprises, non-profit enterprises have also been established to register patient data that may be useful in determining candidate suitability for clinical trials. Examples of non-profit electronic registries include the North American Rheumatoid Arthritis Consortium (NARAC) registry, the American Rheumatism Association Medical Information System (ARAMIS), the National Data Bank for Rheumatic Diseases (NDB) and the Analysis of Medical Practice and Health Outcomes in Rheumatoid Arthritis (AMPHORA) Study. These non-profit electronic registries compile information collected by physicians that relates to chronic diseases and are for the most part used by academic researchers.

In addition to the above non-profit electronic registries, other electronic registries exist. For example, the Mayo Lung Cancer Specimen Registry is an investigational cancer registry that collects tissue samples and patient data for research and investigative purposes. The information and biological samples in the electronic registry are explicitly linked to development of the clinical trial process. The registry lists Mayo-sponsored clinical trials and forms the foundation for current and future clinical trials for lung cancer performed by Mayo Clinic investigators.

Companies that collect biological samples and disease information on a commercial basis to build ethnic population databases for gene discovery, pharmacogenomics and/or therapeutic delivery based on genetic profile also exist. Examples of such companies include deCODE Genetics, Newfound Genomics, Myriad Genetics and Galileo Genomics, and Framingham Genomics Medicine Inc.

The databases associated with deCODE Genetics, Newfound Genomics, and Framingham Genomics Medicine Inc. compile information on individuals, whether healthy or diseased, of a specific ethnic or geographical group and are not necessarily disease-based. This approach is less amenable to use for clinical trials that depend on performing trials in diseased individuals.

Myriad Genetics maintains a proprietary database for product discovery purposes and leverages its access to population-based databases to become a fully integrated biopharmaceutical company involved in gene discovery, drug target identification, drug development and pharmacogenomic product development.

Although enterprises to assist in the recruitment of candidates for clinical trials and to maintain electronic registries exist, these enterprises have not increased the speed by which suitable candidates for clinical trials are enrolled to the extent desired. Thus, a need exists for improvements in the manner by which potential candidates for clinical trials are determined.

There is also a need to evaluate the cost-effectiveness of new and old drugs, technologies and service to improve the quality of care as well as health care policies at a lower cost than currently exists. In order to achieve this, population-based data is very important to provide the desired accurate global picture. Although registries including population-based data are available, problems exist in that the registries tend to have a selection bias.

While treatment and early prevention are important, prevention of disease has the greatest potential to reduce the burden. As a result, there exists a need for a disease management system that fosters the creation of a link between patients, clinicians, researchers and industry.

It is therefore an object of the present invention to provide a novel system and method of facilitating the determination of candidates eligible for a clinical trial. It is also an object of the present invention to provide a novel system and method for disease management and surveillance.

Summary Of The Invention

According to one aspect of the present invention there is provided a method of facilitating the determination of candidates eligible for a clinical trial comprising the steps of:

maintaining an electronic patient registry including patient information relating to a plurality of individuals; and

when individuals are needed for a clinical trial, searching the patient registry based on criteria established for said clinical trial to determine potential candidates within said patient registry that are eligible for said clinical trial.

Preferably, the method further includes contacting the potential candidates to determine if the potential candidates wish to participate in the clinical trial. Consideration is obtained from the entity for conducting the search. The consideration in the preferred embodiment is a monetary fee.

Preferably, the method further includes the step of maintaining a clinical trial registry to receive criteria for clinical trials from a plurality of entities wishing to conduct clinical trials. It is also preferred that the method further includes maintaining a disease management registry to store clinical development and pharmaceutical product information relating to clinical trials that have been conducted as well as disease surveillance data. The clinical development and pharmaceutical product information can be used by entities to generate pharmacoeconomic data and the disease surveillance data can be used to increase the efficiency of therapeutic delivery tools.

According to another aspect of the present invention there is provided a method for disease management comprising the steps of:

maintaining a database populated with patient-derived data relating to a condition of interest, said patient-derived data being acquired from a plurality of difference sources; and

providing said patient-derived data to an entity for study and/or analyzation.

The present invention provides advantages in that since patient data entered into the electronic patient registry is automatically examined to determine if the patient data fits the inclusion and exclusion criteria of a clinical trial in the clinical trial registry, eligible candidates for clinical trials can be determined quickly and efficiently. This of course allows candidates to be enrolled in clinical trials faster thereby significantly reducing the overall time taken to recruit for clinical trials. Clinical trials can be completed more quickly thereby reducing the time to first patient metric for patients in the clinical trials. Also, since patients can opt to participate in clinical trials on line, a comprehensive electronic patient registry is maintained. This allows the search for candidates to be focussed, which speeds up the recruitment process and reduces costs.

The present invention also provides advantages in that since the patient data in the electronic patient registry can be linked to a biological sample registry, a comprehensive source of biological data for pharmacogenomic studies can be maintained.

Brief Description Of The Drawings

An embodiment of the present invention will now be described more fully with reference to the accompanying drawings in which:

Figure 1 is a schematic diagram of a system for facilitating clinical trial recruitment and disease management and surveillance;

Figure 2 is a schematic diagram of a clinical trial subsystem and a disease management subsystem forming part of the system of Figure 1;

Figures 3a to 3e are profile web pages completed by the system administrator in order to register a new physician/investigator, sponsor and centre in the system of Figure 1;

Figure 4 is a block flow diagram of information available to a sponsor accessing the system of Figure 1 via an on-line Internet connection;

Figure 5a is a query web page showing the inclusion and exclusion criteria established for a query of an electronic patient registry;

Figure 5b is a web page showing the results of a query of the electronic patient registry;

Figure 6 is a block flow diagram of information available to a physician/investigator accessing the system of Figure 1 via an on-line Internet connection;

Figures 7a to 7c show a clinical trial web page questionnaire completed by a patient prior to participating in a clinical trial; and

Figure 8 is a block flow diagram of information available to a patient accessing the system of Figure 1 via an on-line Internet connection.

Detailed Description Of The Preferred Embodiment

The present invention relates to a method and system for facilitating clinical trial recruitment and for disease management and surveillance relating to a particular condition of interest. The system maintains an electronic patient registry in which patient data associated with consenting patients that is received from physicians is stored. The patient data stored in the electronic patient registry can be searched against inclusion and exclusion criteria established by sponsors interested in sponsoring clinical trials to determine patients who fit the criteria. The system also maintains a database that stores data relating to centres associated with the condition of interest, physicians/investigators within the centres who conduct the clinical trials relating to the condition of interest and sponsors who sponsor

clinical trials. Further specifics of the system will now be described with reference to Figures 1 to 8.

Turning now to Figure 1, the system for facilitating clinical trial recruitment and for disease management and surveillance relating to a particular condition of interest in accordance with the present invention is shown and is generally identified by reference numeral 10. In this particular embodiment, the system 10 facilitates clinical trial recruitment and disease management and surveillance relating to Rheumatoid Arthritis (RA). Those of skill in the art will however appreciate that the system 10 may be set up to facilitate clinical trial recruitment and disease management and surveillance relating to basically any disease of interest.

As can be seen, system 10 includes a clinical trial subsystem 12, a disease management subsystem 14 and a disease surveillance subsystem 16. The clinical trial subsystem 12 communicates with a biological sample registry 20 over a communications link. The clinical trial subsystem 12 and the disease management subsystem 14 also communicate with clinical trial centres 22, clinical trial sponsors 24, physicians/investigators 26 and patients 28 over communications networks. Disease surveillance system 16 receives information from a government health database 18 and from patients 28.

The clinical trial subsystem 12 and the disease management subsystem 14 are based on the Adaapt software platform created by Empatheon Inc. of California. This software platform integrates data from multiple and far reaching data sources, analyzes and turns the data into meaningful information and personalizes the delivery of the meaningful information to users based on predefined user preferences. The Adaapt software platform provides built-in multi-level security for information. This security includes transport-level security to encrypt the secure socket layer of the HTTP protocol during communications between web servers and client computer systems. A firewall is used to isolate database and file servers from the Internet. User-access protection by assigning user ID numbers and passwords and data-level protection by encrypting data with the system are also implemented.

Figure 2 better illustrates the clinical trial subsystem 12 and the disease management subsystem 14. As can be seen, clinical trial subsystem 12 includes a web server 30 and a fax server 32, both of which are connected to database and file servers 34. Database and file servers 34 manage an electronic patient registry 36 storing physician-derived patient data associated with patients 28 who suffer from RA. In order for a physician to add a patient to the electronic patient registry, the patient must first provide the physician 26 with informed

consent. Once informed consent has been given, the physician can enter physician-derived data associated with the patient into the electronic patient registry 36 through the completion of questionaires. The informed consent also allows the patient data to be used to identify the patient's eligibility for a clinical trial. Each patient 28 whose patient data is stored in the electronic patient registry 36 is assigned a unique patient ID number. In the present embodiment, the patient ID number uses patient billing numbers to link the physician-derived data with federal and provincial health data. Once the patient 28 has been assigned a patient ID number, the patient can access the system 10 on-line as will be described.

Database and file servers 34 also manage a clinical trial registry 38 that stores a list of the clinical trials registered in the system 10 and a list of the sponsers 24 who have submitted the clinical trials. The clinical trials are submitted by sponsors who wish to use the electronic patient registry 36 to determine potential candidates that are eligible for the clinical trials. Each clinical trial listed in the clinical trial registry 38 is identified by title, summary, objective, trial start and end dates, enrollment start and completion dates, inclusion and exclusion criteria, the investigators 26 who have agreed to conduct the clinical trial and profile information identifying the sponsor 24 of the clinical trial. Each sponsor 24 in the list is identified by sponsor ID number, company name, location and contact particulars and status.

The clinical trial subsystem 12 allows sponsors 24 registered with the system 10 to submit clinical trials that include inclusion and exclusion criteria for candidates, to the subsystem. A manager at the clinical trial subsystem 12 stores the information in the clinical trial registry 38 and then uses this information to generate a query of the electronic patient registry 36 to determine quickly and efficiently the patients in the electronic patient registry who fit the criteria. The manager, in turn notifies the physicians/investigators 26 associated with the eligible patients and asks the physicians/investigators 26 to conduct the clinical trial, and if yes then obtain regulatory approval for the clinical trial and contact the patients to recruit and enrol the patients in the clinical trial.

The disease management subsystem 14 also includes a web server 50 and a fax server 52, both of which are connected to database and file servers 54. The database and file servers 54 manage a disease management registry 56 that stores a list of the clinical trial centres 22 and the physicians/investigators 26 associated with the centres who conduct clinical trials relating to RA. Each centre 22 in the list is assigned a unique centre ID number. Profile information identifying each centre 22 is also stored such as the name of the centre, location and contact particulars and status (i.e. whether the centre is active or

inactive). Each physician/investigator 26 in the list is assigned a unique investigator ID number. Profile information identifying each physician/investigator is also stored such as the name of the investigator, location and contact particulars, specialty and status (i.e. whether the centre is active or inactive).

The disease management registry 56 also stores patient-derived data and information that assists users to create policy and healthy environments to lessen the burden of RA as well as information that helps users to choose lower risk behaviours that will will lessen the burden of RA. In this manner, the disease management subsystem 14 can provide cost-effective clinical development and product commercialisation information to users that fosters the creation of a link involving patients with RA, clinicians, researchers and industry. The patient-derived data in the disease management registry 56 and the physician-derived data in the electronic patient registry 36 that that relates to the same patient is linked. Thus, the disease management subsystem 14 provides patient-derived data as a product linked to physician-derived data when the data relates to the same patient.

The web servers 30 and 50 allow patients 28, physicians/investigators 26, sponsors 24 and centres 22 to access the subsystems 12 and 14 on-line over an Internet connection through client computer systems that execute web client applications in the form of web browsers. As is well known, the Internet provides a backbone of high-speed data communication lines between host computers that route data and messages using the TCP/IP suite of protocols. During communications between the web servers 30 and 50 and client computer systems, the web servers send web page source files that include Hypertext Markup Language (HTML) code to the client computer systems in response to requests generated by the web browsers. The HTML code received by the client computer systems causes the web browsers to display formatted web pages to the users of the client computer systems. This enables the users to access and interact with the subsystems 12 and 14 through web-based graphical user interfaces.

The fax servers 32 and 52 allow information received from patients 28, physicians/investigators 26 and sponsors 24, who do not have access to the Internet, to submit information to the subsystems 12 and 14 by facsimile. Information received by the fax servers 32 and 52 is scanned and conveyed to the appropriate database server for storage in the appropriate registry or database.

The biological sample registry 20 stores urine, serum and cell samples of blood and synovial fluid and surgical specimens associated with patients 28 in the electronic patient registry 36. The urine, serum and cell samples of blood and synovial fluid and

surgical specimens are collected from patients 28 with their consent. The physician-derived data in the electronic patient registry 36 and the serum and cell samples in the biological sample registry 20 that are associated with the same patient are linked thereby to enhance the utility and impact of the electronic patient registry 36. This is due to the fact that the combination of physician-derived patient data and biological data facilitates studies of biomarkers, genomics (the identification of disease associated genes) and pharmacogenomics (the identification of genes associated with therapeutic outcomes).

The information stored in the registries 36 and 38 of subsystem 12 and in the registry 56 of subsystem 14 is managed by a system administrator. Physicians/investigators 26, sponsors 24 and centres 22 wishing to be listed the system 10 must be registered. Registration requires the submission of appropriate profile information referred to previously to the system administrator. This information is used by the system administrator to complete and save profile forms. Figures 3a to 3e show the profile forms completed by the system administrator in order to register a new physician/investigator 26, sponsor 24 and centre 22. Physicians/investigators 26 and sponsors 24 who have registered with the system 10 are assigned unique ID numbers and passwords that can be used to login into the system 10. The system administrator also has the necessary rights to access all of the information in the registries 36 and 38 and the database 56. Thus, the system administrator can edit and delete the profiles associated with physicians/investigators 26, sponsors 24 and centres 22 that are stored in the database 56.

When a sponsor 24 establishes an on-line Internet session with the system 10 via their client computer system, by entering the uniform resource locator (URL) of the system website into the web browser, the sponsor can log into the system 10 by entering their ID number and password. Once logged in, the sponsor 24 has the option to access the clinical trial subsystem 12 or the disease management subsystem 14 as shown in Figure 4. If the sponsor 24 opts to access the clinical trial subsystem 12, the sponsor has access to clinical trial services (block 100) including recruitment, consulting and marketing services (blocks 102 to 106) provided by the system 12. If the sponsor 24 selects the recruitment services 102, the sponsor is able to submit a clinical trial to the subsystem 12 for storage in the clinical trial registry 38. The sponsor 24 is charged consideration in the form of a monetary fee for submitting a clinical trial that results in a query of the electronic patient registry 36 being made.

During submission of a clinical trial, the sponsor 24 completes a profile for the clinical trial and classifies the clinical trial into one of three classifications, namely public,

summary and private. All physicians/investigators 26 have access to the profile of a public clinical trial. With respect to clinical trials classified as summary, only select physicians/investigators have access to the profiles of these clinical trials. Summary information concerning the clinical trials is however available to all physicians/investigators 26. With respect to clinical trials classified as private, only select physicians/investgators have access to the profiles of these clinical trials. No information is available to non-selected physicians/investigators 26.

Once the sponsor 24 has submitted a clinical trial, the manager stores the clinical trial in the registry 38 and then uses the inclusion and exclusion criteria in the submitted clinical trial to perform a query of the electronic patient registry 36. During the query process, the manager is presented with a query web page that exposes a search engine as shown in Figure 5a. The search engine includes a number of criteria fields each with associated condition and value fields together with Boolean logic fields. The manager in turn enters the appropriate information into the fields and then links the fields with the appropriate Boolean logic to establish the inclusion and exclusion criteria to be used during the query. The query is then initiated causing the search engine to query the electronic patient registry 36 based on the established inclusion and exclusion criteria. When the query is complete, the query results are presented to the manager on a web page as shown in Figure 5b. As can be seen, the web page presents a list of the patients that fit the inclusion and exclusion criteria and the status of the patients in the list (i.e. whether they have agreed to participate in clinical trials).

Once the query has been completed, the manager contacts them of physicians/investigators 26 associated with the patients identified in the query to notify them of their patients that match inclusion and exclusion criteria for a clinical trial. The manager asks the physicians/investigators 26 to agree to conduct the clinical trial, obtain regulatory approval to conduct the clinical trial and then enrol their patients in the clinical trial.

In addition to the clinical trial services 100, the sponsor 24 can view a list of their clinical trials stored in the clinical trial registry 38 (block 108). The sponsor also has access to additional resources (block 110) as well as access to the profiles associated with their clinical trials stored in the clinical trial registry 38 (block 112). Information concerning the patients enrolled in the sponsor's clinical trial is also available. If the sponsor wishes disease management data associated with these patients, the sponsor can pay a fee for this information.

If the sponsor 24 accesses the disease management subsystem 14, the sponsor has access to the list of centres 22 and the list of the physicians/investigators 26 that are stored in the database 56 (blocks 114 and 116). The sponsor also has access to recent news relating to RA that has been posted to the subsystem 14.

When a physician/investigator 26 logs into the system 12, the physician/investigator is presented with a home page that displays news and information, new publications, reminders and messages to the physician/investigator 26. From the home page, the physician/investigator 26 can navigate either to the clinical trial subsystem 12 or to the disease management system 14 as shown in Figure 6. If the physician/investigator 26 opts to access the clinical trial subsystem 12, the physician/investigator has access to clinical trial services (block 200) that include recruitment, consulting and marketing services (blocks 202 to 206).

When the physician/investigator 26 is notified by the manager of their patients who fit the inclusion and exclusion criteria of clinical trials, if the physician/investigator 26 is interested in conducting the clinical trial and enrolling their patients, the physician/investigator 26 must obtain regulatory approval for the clinical trial by submitting the appropriate forms, dealing with ethics, and executing the appropriate clinical trial agreements. Once the physician/investigator 26 has completed the regulatory requirements, the system administrator adds the physician/investigator to the list in the registry 56 for the clinical trial and enables the physician/investigator to enroll patients for the clinical trial.

In addition, the physician/investigator 26 can view a list of the clinical trials stored in the clinical trial registry 38 (block 208). Through the clinical trial registry, the physician/investigator can view the profiles of clinical trials designated as public and clinical trials designated as summary and private for whom the physician/investigator 26 has been selected (block 210). Also, the physician/investigator 26 can enter patient data for a new patient wishing to participate in a clinical trial. The patient data is stored in the electronic patient registry 36. This is achieved by completing and submitting the appropriate form as shown in Figures 7a to 7c. As can be seen, the form includes questions regarding what drugs the patient is on, when they were started and stopped, and why they were stopped. These three questions plus erythrocyte sedimentation rates, answers to the health assesment questionaire (HAQ) and annual X-rays enables the patient data in the electronic patient registry 36 to be used in conjunction with biological samples stored in the biological sample registry 20 for pharmacogenomics purposes. When patient data for the new patient wishing

to participate in a clinical trial is entered into the electronic patient registry 36, a query of the electronic patient registry can be made to determine if the patient data fits the inclusion and exclusion criteria associated with any of the clinical trials in the clinical trial registry 38.

The physician/investigator 26 can also access information relating to the clinical trials in which the physician/investigator is currently participating (block 214). This information includes general information about the clinical trial, the regulatory status of the clinical trial, a list of all the patients that the physician/investigator 26 has enrolled in the clinical trial as well as a summary of the number of patients enrolled in the clinical trial by all other physicians/investigators.

If the physician/investigator 26 accesses the disease management subsystem 14, the physician/investigator has access to the list of centres 22 and the list of investigators that are stored in the registry 56 (blocks 220 and 222). The physician/investigator 26 also has access to recent news relating to RA that has been posted to the subsystem 14 (block 224). In addition, the physician/investigator can access a list of the physician/investigator's patients who are participating in clinical trials (block 226) but does not have access to data from any other physician's patients. From the list, the investigator can see which clinical trials each patient is participating in and can access each patient's profile. The physician/investigator can also access a search engine similar to that shown in Figure 5a and conduct queries of the patient data in the electronic patient registry 36 that is associated with the physician/investigator's patients. The patient's profile provides contact information allowing the physician/investigator to contact the patient directly (block 228). Access to the patient's profile also allows the physician/investigator to update the patient data in the electronic patient registry 36 (block 230).

The disease management subsystem 14 also provides an ethics area and a messaging area. The ethics area presents information relating to ethics committees, whether ethics memberships have been submitted to the system 10, the frequency of ethics meetings and the frequency of submissions for new proposals. The messaging area allows the physician/investigator to send secure messages to the system administrator and to sponsors 24.

When a patient 28 accesses the system 10, the patient has the option to access the clinical trial subsystem 12 or the disease management subsystem 14 as shown in Figure 8. If the patient opts to access the clinical trial subsystem 12, the patient can view the list of clinical trials in the clinical trial registry 38 (block 300) and can elect to participate in a clinical trial by selecting a clinical trial from the list and completing and submitting a

recruitment form (block 302). This changes the patient's status in the electronic patient registry 36 to active. The patient 28 can also access information concerning available clinical trials including a list of the centres 22 conducting clinical trials (block 304) and frequently asked questions (block 306).

If the patient 28 opts to access the disease management subsystem 14, the patient can view their patient data that is stored in the electronic patient registry 36 (block 310) and their physician's contact information to allow the patient to contact their physician directly (block 312). The patient can also access the list of the centres in the database 56 (block 314) and the list of physicians/investigators 26 in the database 56 (block 316).

The system administrator monitors the system 10 and generates reports on a regular basis for the sponsors 24 of clinical trials. For each clinical trial, a report is generated that includes an update on the physicians/investigators regulatory status and the patient enrolment by each physician/investigator for the clinical trial.

As will be appreciated, the clinical trial subsystem 12 facilitates the recruitment of candidates for clinical trials thereby speeding up the recruitment time. This is due to the fact that patients can access the clinical trial subsystem 12 on-line and elect to participate in clinical trials. Patient data entered into the electronic patient registry is compared with the inclusion and exclusion criteria of clinical trials allowing eligible candidates for the clinical trials to be determined quickly and efficiently and then contacted to enrol in the clinical trials.

Although the clinical trial subsystem 12 is described as using a manager to populate the clinical trial registry 38, conduct the electronic patient registry query and notify physicians/investigators 20 if their patients fit the criteria of clinical trials, those of skill in the art will appreciate that this process can be automated. In this way, clinical trials can be submitted electronically to the clinical trial subsystem 12 for storage in the clinical trial registry 38. Once in the clinical trial registry, the inclusive and exclusive criteria can be retrieved automatically and used during an electronic patient registry query. Physicians/investigators whose patients fit the criteria can then be notified electronically.

Satellite terminals are installed at the offices and clinics of physicians/investigators 26 and execute web client applications such as web browsers. When a patient visits a physician/investigator for an appointment, the patient is asked to access a health questionnaire (block 318) through the disease management system 14 and answer the questionnaire. The information entered by the patient is incorporated into the database at the office or clinic and is compared with prior data to generate a historical summary based on the

physician's preferences (i.e. medications, HAQ score, pain scale, joint count over time etc.). The results of the comparison are presented to the physician in graphical format prior to the physician's meeting with the patient. This conserves time for the physician and the patient and provides the physician with a database tool that can be used to better manage patient workload. The information is also transmitted to the system for storage in the registry 56.

The web browser executed by each satellite terminal provides a host of other useful links that are customisable by the physician/investigator. For example, the web client application can be customized to provide links to news including clinical research updates, e-journals, to self-administered patient records (SAPRs) created by the patient at the office, patient-physician communications, medical resources, links to on-line search engines, links to university and other medical library catalogues, websites with RA content, news sources, disease indexes and factual information, books and shopping, related goods and services such as vendor catalogs and other services. Information relating to RA acquired from these links and sources can be stored in the registry 56.

SAPRs created by patients are stored in the registry 56 and constitute patient-derived data. Patients can annotate their SAPRs with visit details so that an electronic record can be self-maintained. SAPRs can be shared with family doctors and specialists by assigning them read-only access to portions of the SAPRs.

Through completion of the SAPRs, health and other questionnaires and website links, the registry 56 stores patient-derived data that includes demographic information, pharmaceutical product use information, psychological counselling information, assisted living device use information, medical device use information, pharmaceutical product side effect information, quality of life information, health care utilisation information, health care education material use information and work place disability information. This information is entered into the disease management registry only after a diagnosis of RA is confirmed with the patient's physician. Information in the disease management registry can be sold to an entity studying and/or analyzing disease management data for consideration in the form of a monetary fee.

As will be appreciated, the disease management subsystem 14 provides a convenient portal for information relating to RA through which patients, healthcare practitioners and allied health professionals, researchers, industry, academia and government can communicate on several levels. The disease management subsystem 14 provides a single point of access for patients to learn and participate in research.

The disease management subsystem 14 also allows patients, consumers, researchers and physicians to access web pages with links to health questionnaires, information, news and other relevant products and services. This enables patients to be able to comparison-shop for a wide variety of goods and professional services, ranging from assistive devices to home renovators.

The disease surveillance subsystem 16 is designed to provide patients with RA practical information about managing and living with their disease, a community to interact with other members, practical life-aid products, and other resources on the Internet. The disease surveillance subsystem is also designed to provide physicians tools for managing patient information, graph longitudinal trends, track disease management progress and outcomes.

To populate the database of the disease surveillance subsystem 16, data from the government health care database is used that relates to RA. This information is obtained by looking for data that includes the appropriate physician diagnostic codes used for billing. Data on all patients who visited a physician where the billing entry included an RA diagnostic code is obtained. The frequency of the diagnostic code, the speciality code of the physician providing the diagnoses and the use of specific medicationsis be taken into consideration to decide which patients are included in the database. The data includes visits to healthcare professionals, hospital visits, interventions, medication used, and laboratory tests ordered.

After the initial population of the database, incidents of RA are identified at regular time intervals (every year). The same methodology described above is used to upate the database.

As part of the validation, the medical and laboratory records of a sub-sample of patients are reviewed to validate the diagnosis of RA. The proposed diagnostic validation exercise is necessary. In order to measure sensitivity and specificity of diagnosis using the proposed approach, a sample of patients who have not been diagnosed with RA, but who have related symptoms are required. This provides a measure of the frequency of false negatives yeilding a population-based database that is not selection biased.

The disease surveillance subsystem enables researchers to ask specific research questions concerning RA, which can be answered at a population level. As a result, the disease surveillance subsystem registry is a resource for individual research projects. For example, the disease surveillance subsystem will enable research to be conducted in:

the evaluation of the impact of different treatment strategies on patients' quality of life and healthcare resource utilisation;

the evaluation of the cost-effectiveness of new interventions;

the study of the demographics of RA within the region where data is being collected;

the compilation of population data on outcome of RA on healthcare resource utilisation;

the performance of health services research;

the evaluation of the impact of healthcare policies;

the evaluation of the impact of socio-demographic factors on outcome of RA;

the assessment of the timeliness of clinical interventions in a population-based setting;

the assessment of access to appropriate, state-of-the art care in a population-based setting;

the description of the patterns of disease severity of RA in a population-based setting; and

the description of the patterns of access / referral to specialists such as rheumatologists in a population-based setting.

Since the database of the disease surveillance subsystem is population-based, it provides a global picture of the health status of people with RA, thereby informing stakeholders on how to improve this condition and providing a tool to measure the impact and outcome of interventions and policies. The database provides unique, current and population-based information. Research conducted using data from the disease surveillance subsystem is used to provide recommendations to healthcare professionals about optimal treatment strategies, by determining the healthcare needs of individuals with the condition of interest, and by providing information that can be used by advocates to influence healthcare policies. Furthermore, data from the disease surveillance subsystem allows an estimate of the real cost of RA at the population level to be made. The data can also be used to reduce costs through cost-effective treatment and healthcare policy recommendations.

Although the system 10 as described above makes particular reference to facilitating recruitment for clinical trials and disease management and surveillance relating to RA., it will be appreaciated that the system is equally applicable to other diseases and/or conditions or interest.

Although a preferred embodiment of the present invention has been described, those of skill in the art will appreciate that variations and modifications may be made without departing from the spirit and scope thereof as defined by the appended claims.

What is claimed is:

1. A method of facilitating the determination of candidates eligible for a clinical trial comprising the steps of:

maintaining an electronic patient registry including patient data relating to a plurality of individuals; and

when individuals are needed for a clinical trial, searching the patient registry based on criteria established for said clinical trial to determine potential candidates within said patient registry that are eligible for said clinical trial.

2. The method of claim 1 further comprising the step of contacting the potential candidates to determine if said potential candidates wish to participate in said clinical trial.

3. The method of claim 2 further comprising the step of obtaining consideration from said entity for conducting said search.

4. The method of claim 3 wherein said consideration is a monetary fee.

5. The method of claim 3 further comprising the step of maintaining a clinical trial registry, said clinical trial registry receiving criteria for clinical trials from a plurality of entities wishing to conduct clinical trials, the criteria for said clinical trials being used during said searching step.

6. The method of claim 5 wherein said searching step is automatically re-performed when patient data in said patient registry is modified.

7. The method of claim 3 wherein the patient information is received from physicians.

8. The method of claim 7 wherein individuals can elect to opt to participate in clinical trials on line.

9. The method of claim 2 wherein the step of contacting the potential candidates includes the steps of contacting each individual's physician and asking the physicians to contact the eligible candidates.

10. The method of claim 2 further comprising the step of maintaining a disease management registry, said disease management registry storing patient-derived data acquired from multiple sources.

11. The method of claim 10 wherein said patient-derived information is selected from the the group consisting of: demographic information; pharmaceutical product use information; psychological counselling information; assisted living device use information; medical device use information; pharmaceutical product side effect information; quality of life information; health care utilisation information; health care education material use information; and work place disability information.

12. The method of claim 10 further comprising the steps of maintaining a disease surveillance registry.

13. The method of claim 10 wherein said clinical development and pharmaceutical product information is used by entities to generate pharmacoeconomic data developed in conjunction with generic information derived from patient biological samples.

14. The method of claim 12 wherein said disease surveillance data is used to increase the efficiency of the delivery of health care information and services in place of therapeutic delivery.

15. A method for disease management comprising the steps of:

maintaining a database populated with patient-derived data relating to a condition of interest, said patient-derived data being acquired from a plurality of difference sources; and

providing said patient-derived data to an entity for study and/or analyzation.

16. The method of claim 14 further comprising the step of acquiring consideration for providing said patient-derived data.

17. The method of claim 15 wherein said patient-derived information is selected from the the group consisting of: demographic information; pharmaceutical product use information; psychological counselling information; assisted living device use information; medical device use information; pharmaceutical product side effect information; quality of life information; health care utilisation information; health care education material use information; and work place disability information.

18. A system for facilitating the determination of candidates eligible for a clinical trial comprising:

an electronic patient registry including patient data relating to a plurality of individuals; and

a search engine responsive to search criteria and searching the patient registry based on criteria established for said clinical trial to determine potential candidates within said patient registry that are eligible for said clinical trial.

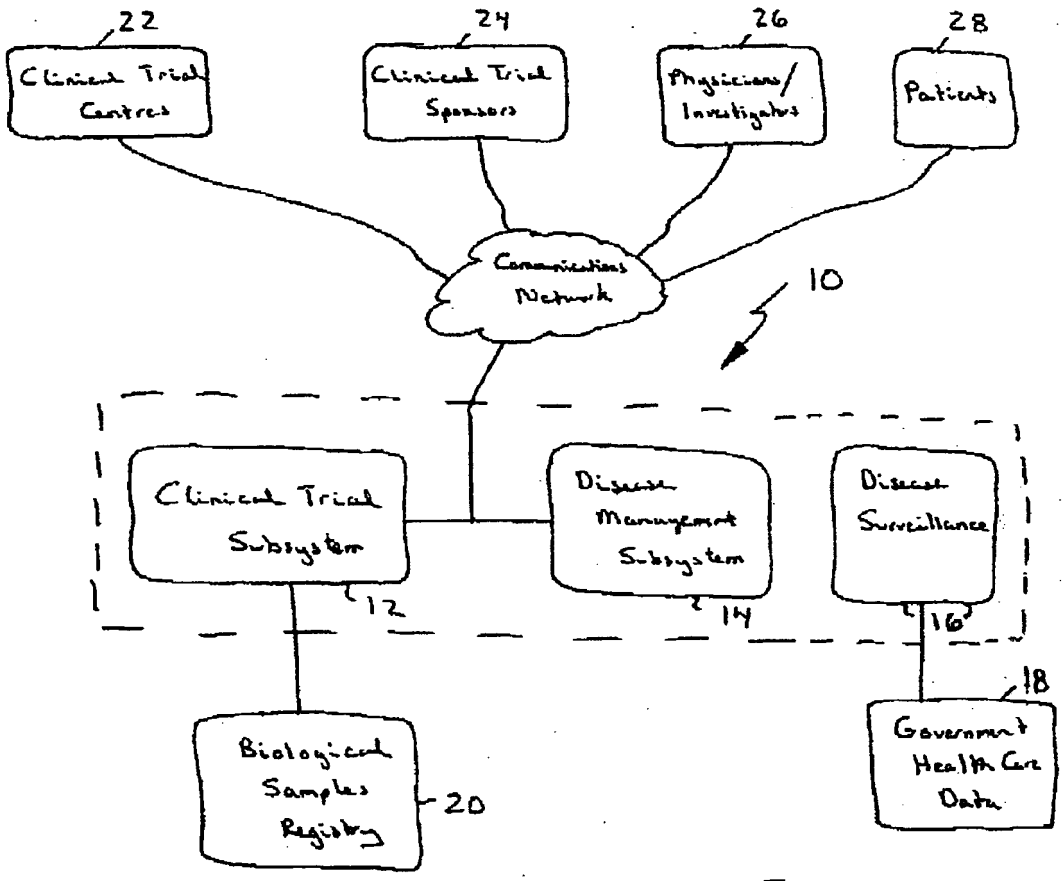

22
Clinical Trial Centres
24
Clinical Trial Sponsors
26
Physicians/ Investigators
28
Patients
Communications Network
10
Clinical Trial Subsystem
12
Disease Management Subsystem
14
Disease Surveillance
16
18
Government Health Care Data
Biological Samples Registry
20

Fig. 1

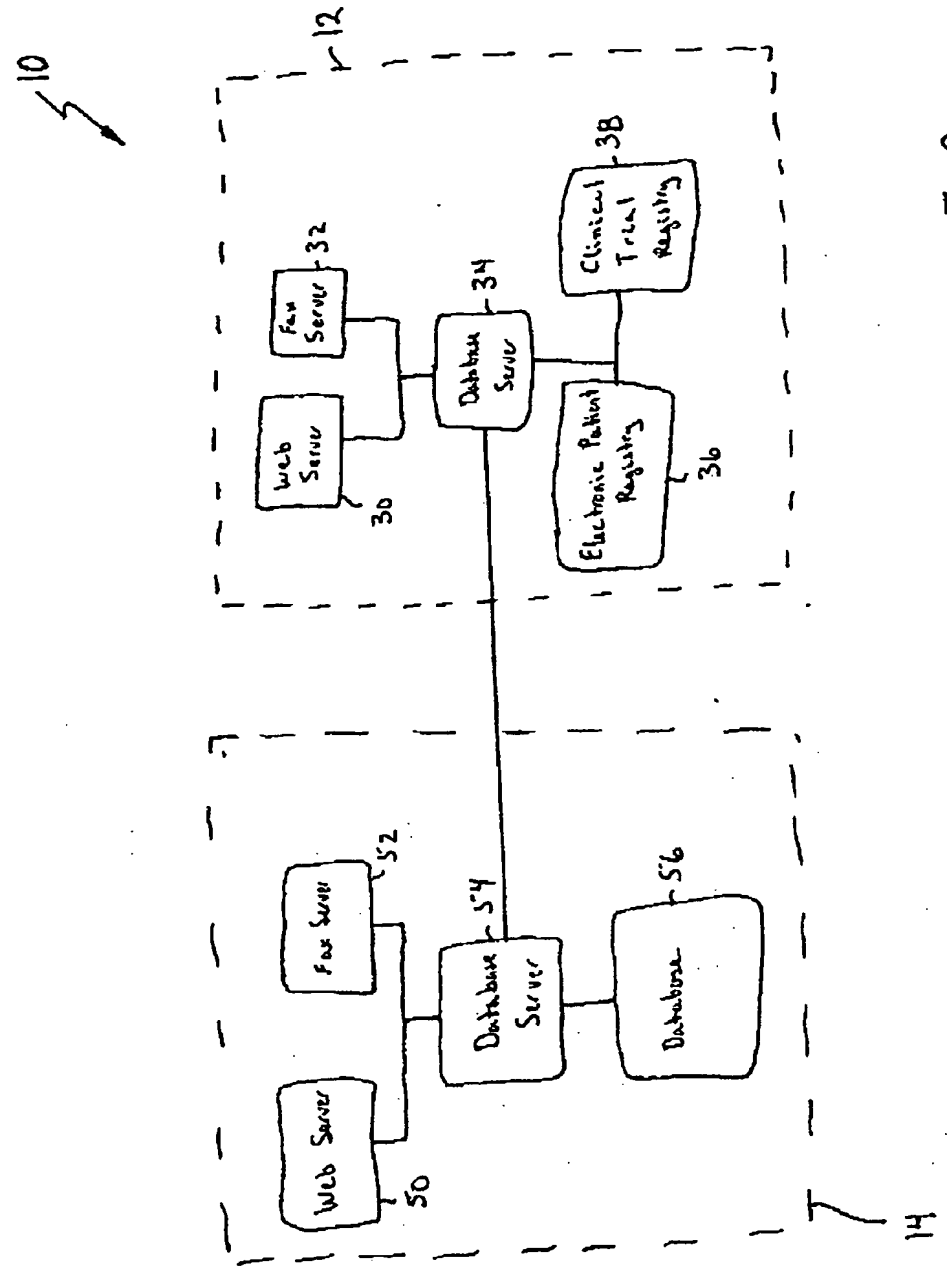

10
12
Fax Server
32
Web Server
30
Database Server
34
Clinical Trial Registry
38
Electronic Patient Registry
36
14
Fax Server
52
Web Server
50
Database Server
54
Database
56

Fig. 2

New Investigator

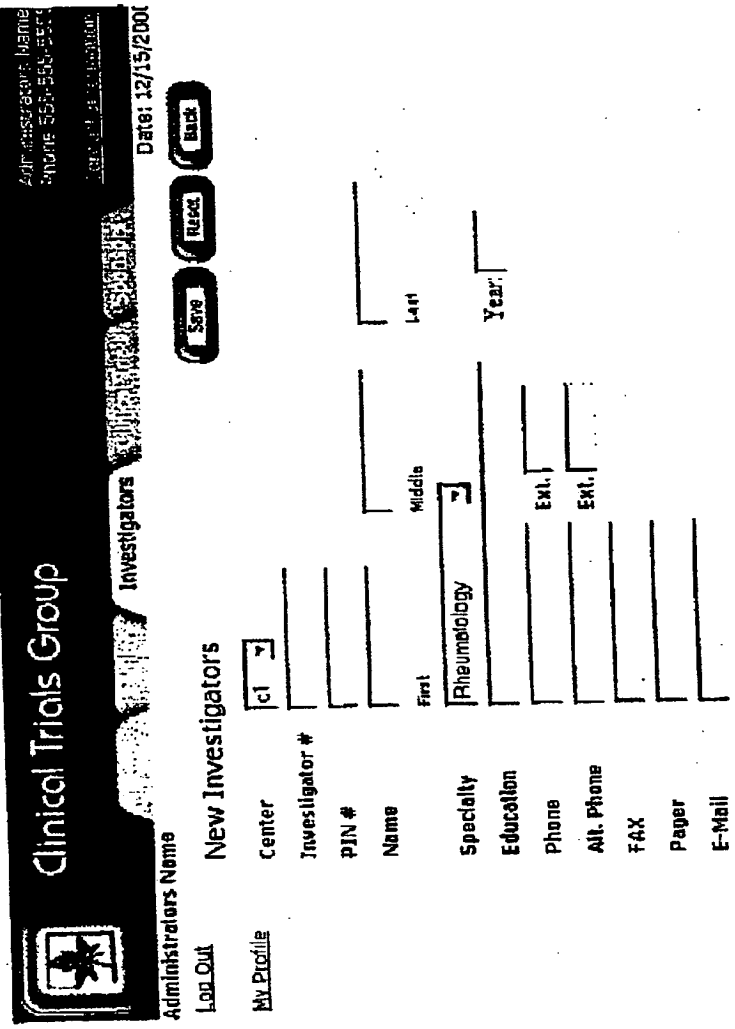
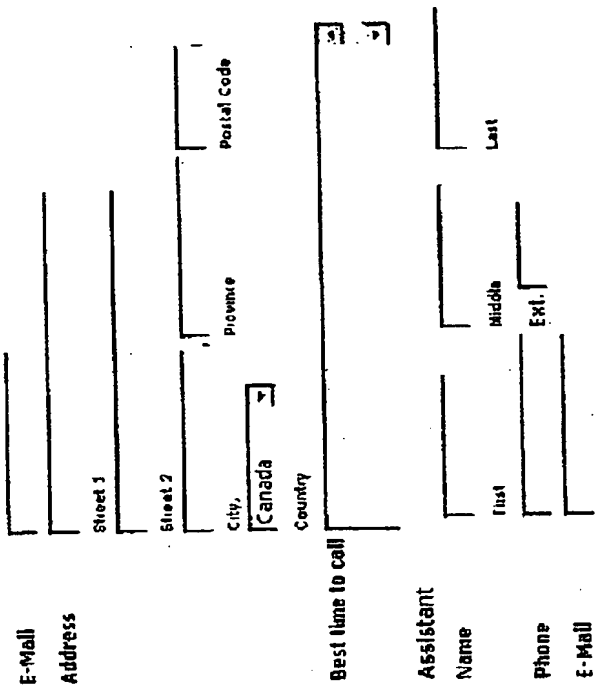
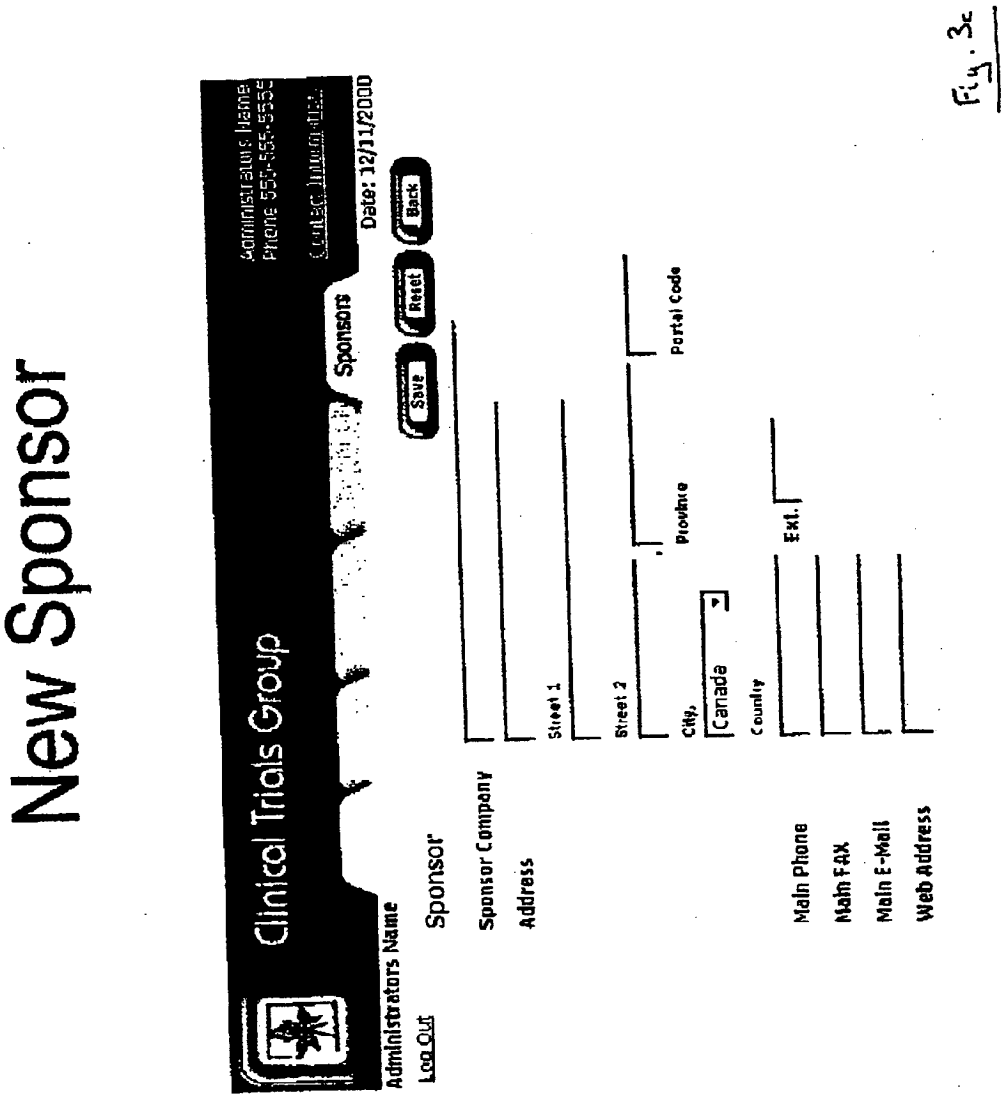


Fig. 3a

Fig. 3b

New Investigator (cont)

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Sponsors
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Reset
Back
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Sponsor
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Province
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Canada
Country
Ext.
Main Phone
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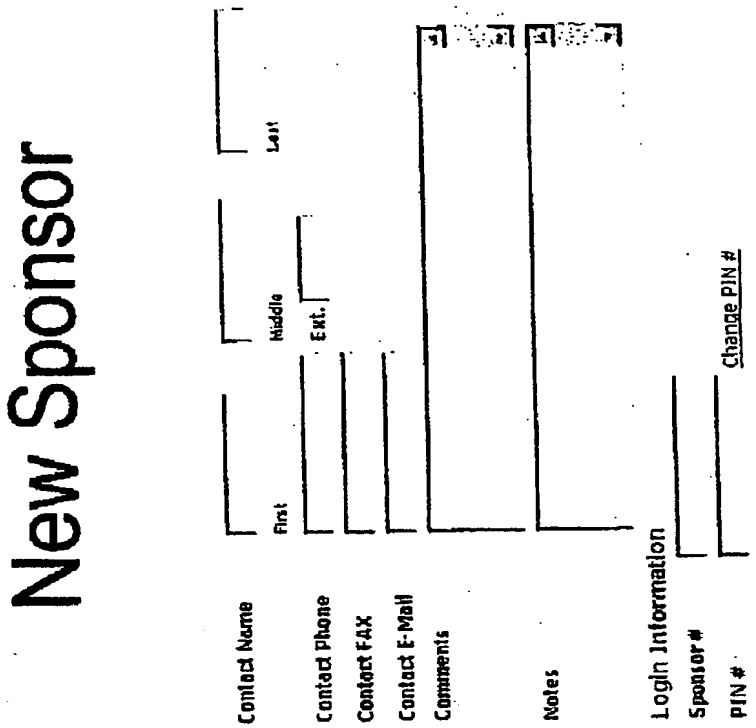
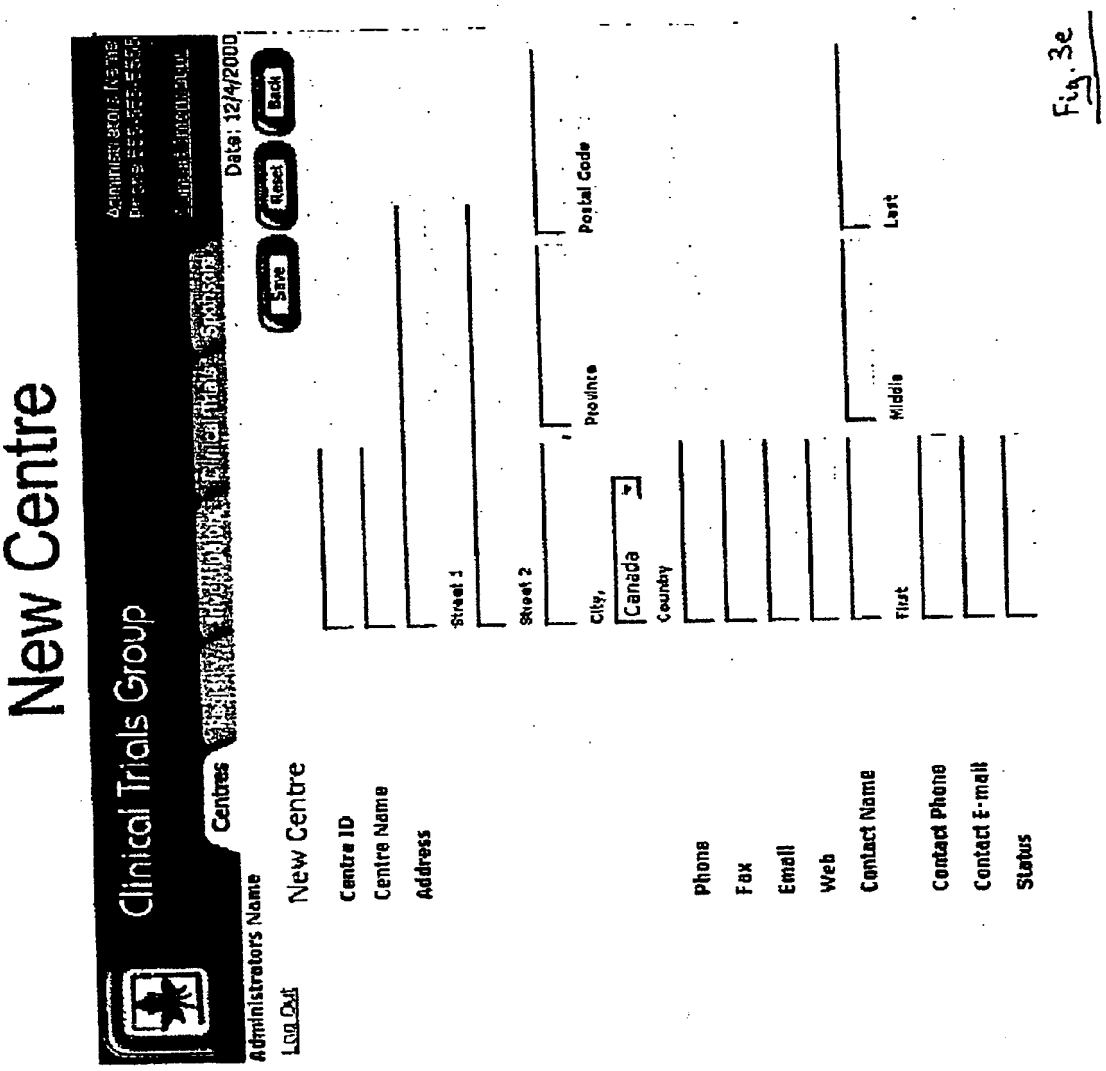
Main E-Mail
Web Address

Fig. 3c

Fig. 3A


New Sponsor
Contact Name
First
Middle
Last
Contact Phone
Ext.
Contact FAX
Contact E-Mail
Comments
Notes
Login Information
Sponsor #
PIN #
Change PIN #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Clinical Trials Group
Centres
Administrators Name
Log Out
New Centre
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Reset
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Centre ID
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Address
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Street 2
City,
Province
Postal Code
Canada
Country
Phone
Fax
Email
Web
Contact Name
First
Middle
Last
Contact Phone
Contact E-mail
Status

Fig. 3e

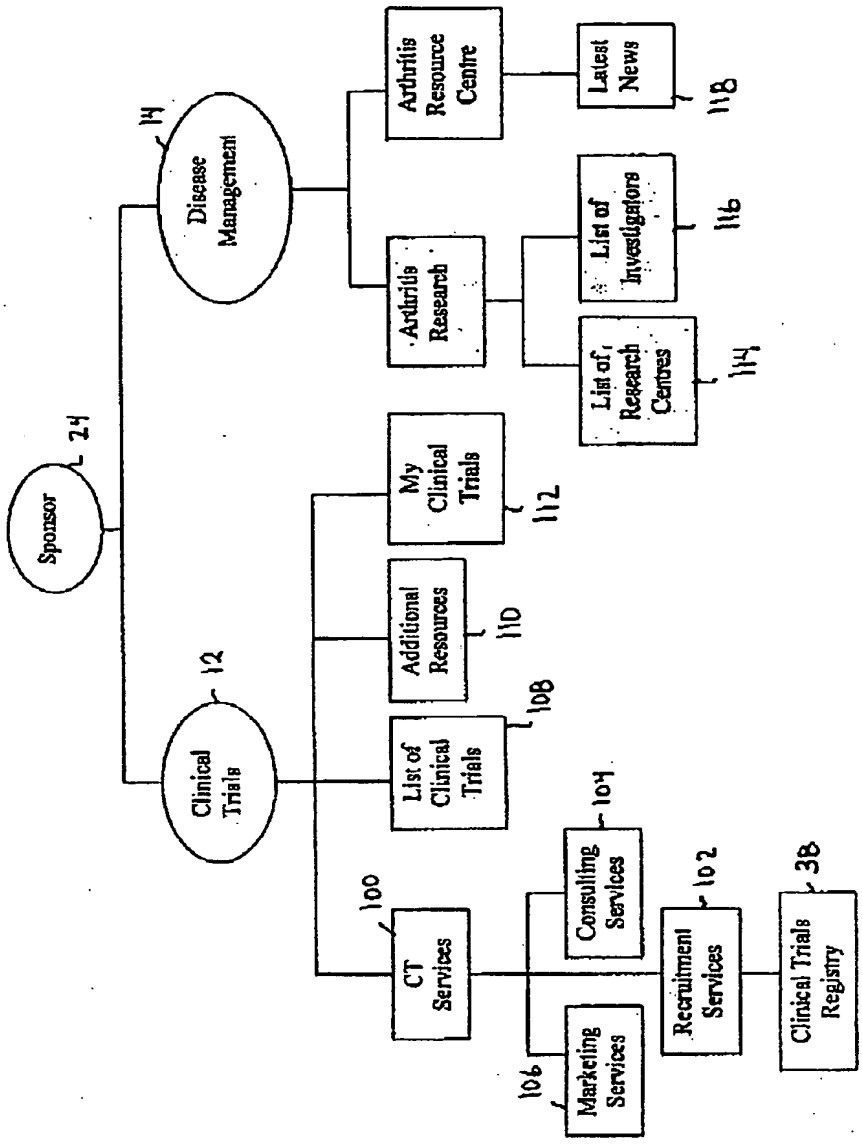

Sponsor
24
Disease Management
14
Clinical Trials
12
Arthritis Resource Centre
Latest News
118
Arthritis Research
List of Investigators
116
List of Research Centres
114
My Clinical Trials
112
Additional Resources
110
List of Clinical Trials
108
CT Services
100
Consulting Services
104
Marketing Services
106
Recruitment Services
102
Clinical Trials Registry
38

Fig. 4

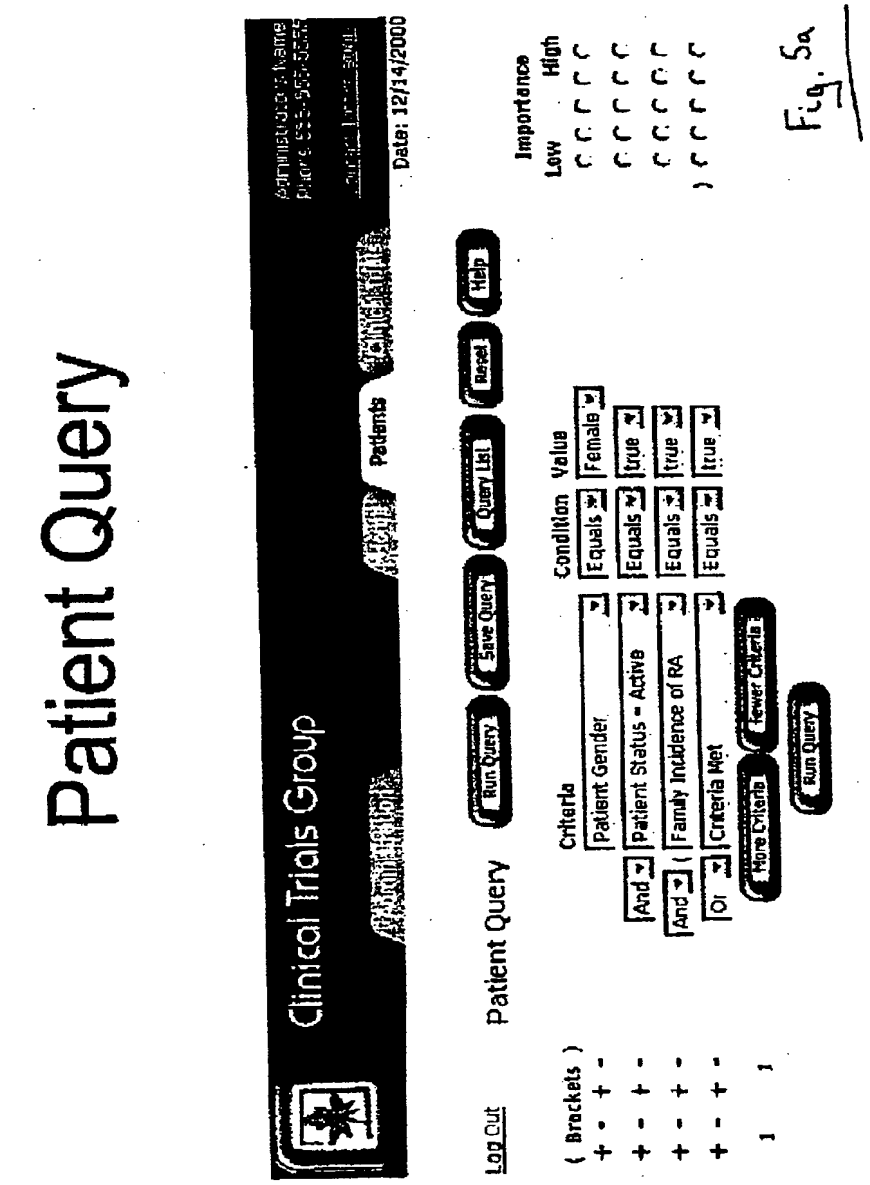

Patient Query
Clinical Trials Group
Patients
Date: 12/14/2000
Log Out
Patient Query
Run Query
Save Query
Query List
Reset
Help
(Brackets)
Criteria
Condition
Value
Importance
Low
High
Patient Gender
Equals
Female
Patient Status = Active
Equals
true
Family Incidence of RA
Equals
true
Criteria Met
Equals
true
And
And
Or
More Criteria
Fewer Criteria
Run Query

Fig. 5a

Patient Query Result

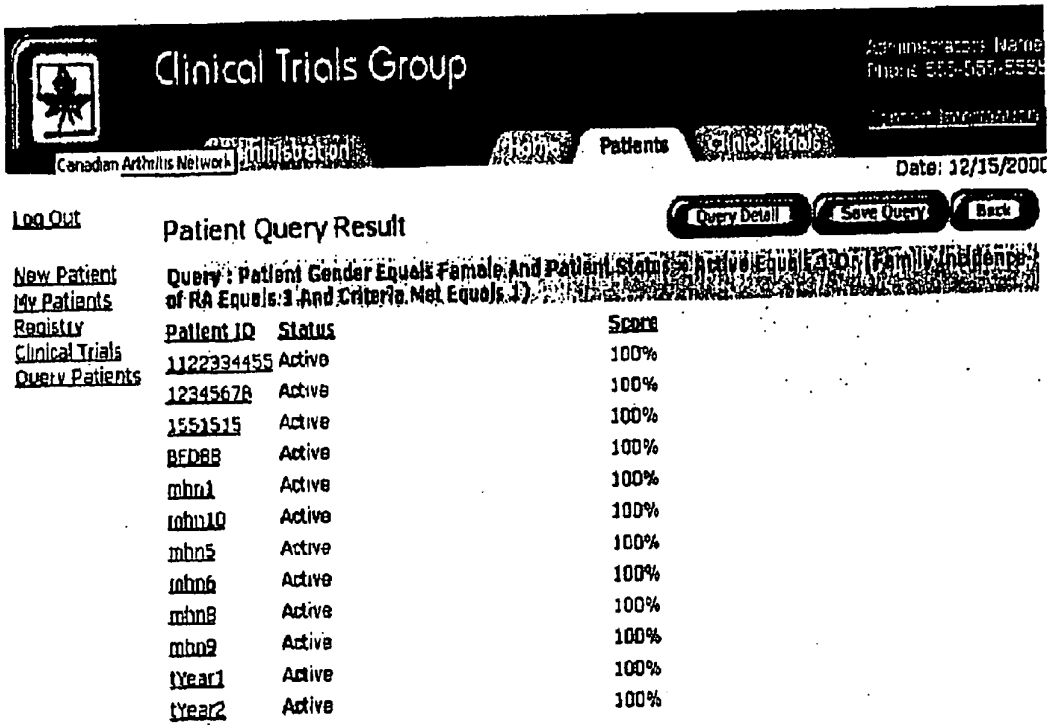


Fig. 5b

Patient Query Result

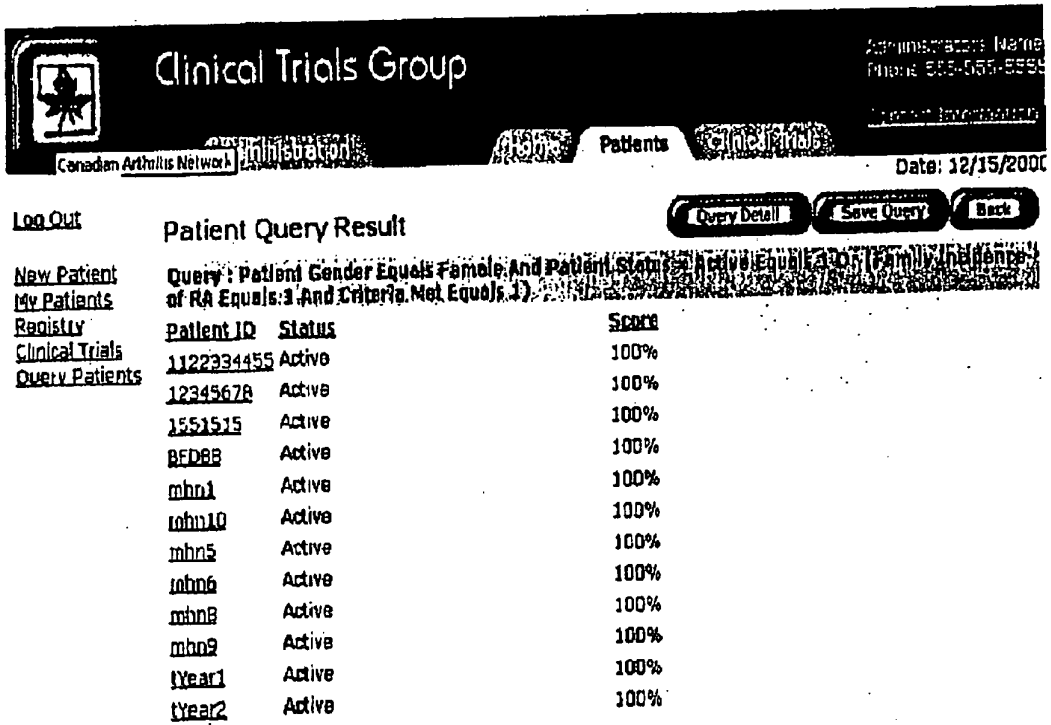
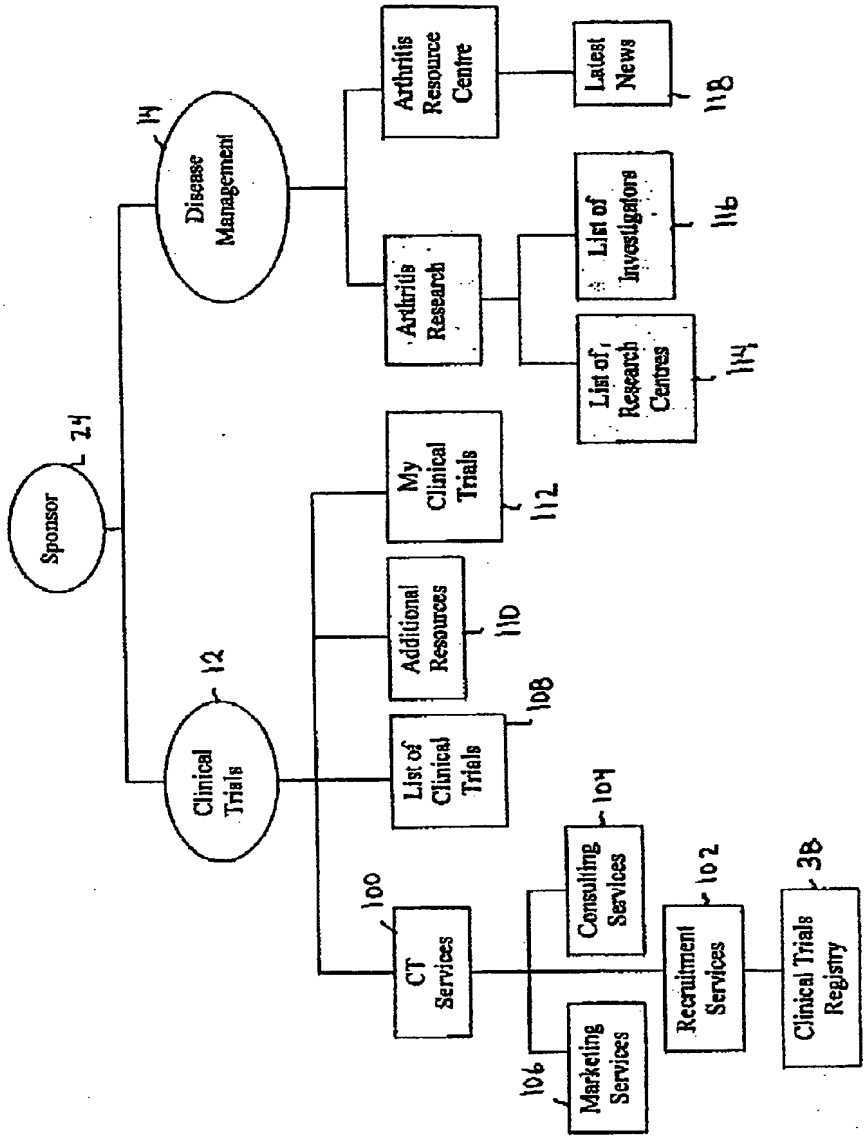


Fig. 5b


Sponsor
24
Disease Management
14
Clinical Trials
12
Arthritis Resource Centre
Latest News
118
Arthritis Research
List of Investigators
116
List of Research Centres
114
My Clinical Trials
112
Additional Resources
110
List of Clinical Trials
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CT Services
100
Consulting Services
104
Recruitment Services
102
Clinical Trials Registry
38
Marketing Services
106

Fig. 4

First Visit Form

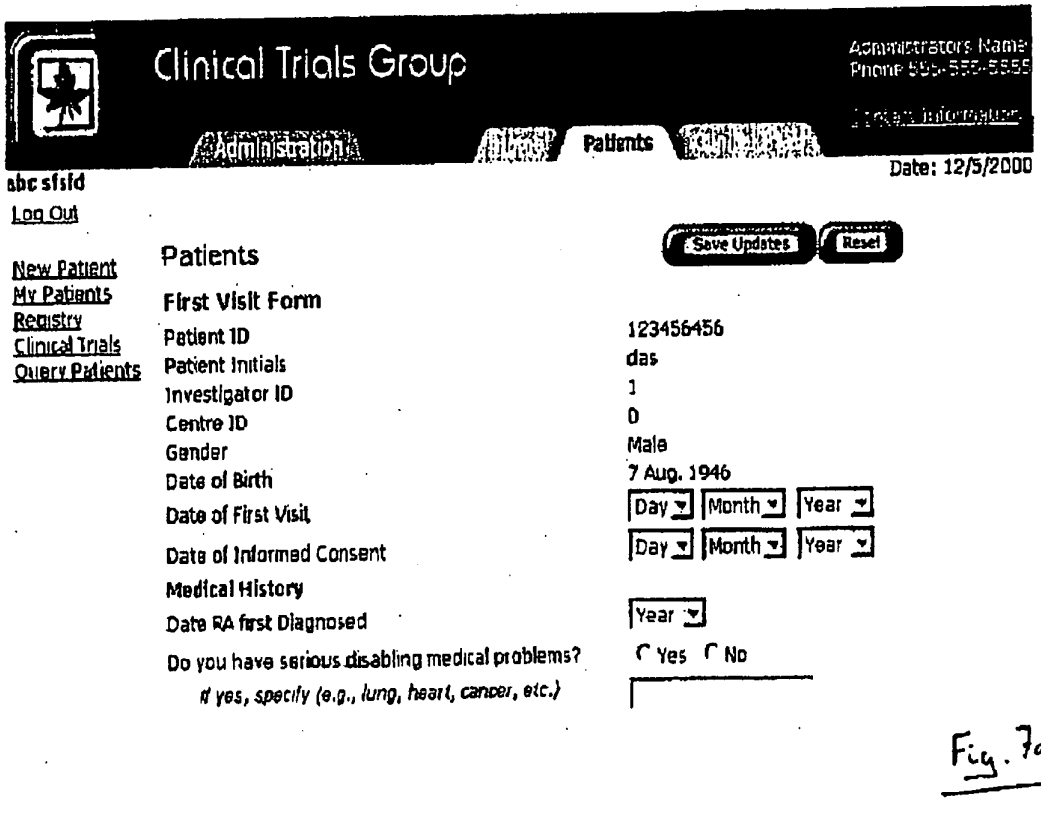

Fig. 7a

First Visit Form (cont)

Family History

Does anyone in your family have RA? ○ Yes ○ No

If yes, specify [ ]

Disease Criteria

Patients to be enrolled must meet the ACR criteria for diagnosis of RA:

(criteria - 4 out of 7)

AM Stiffness	☐
Symmetrical	☐
RF Positive	☐
Hand-involvement	☐
>3 Joints	☐
Nodules	☐
Radiologic changes	☐

Disease Assessment

	Qty.	<5	5-15	>15		
Tender Joints (0-66)	( )	○	○	○	○ No Data	Optional
Swollen Joints (0-68)	( )	○	○	○	○ No Data	Optional
AM Stiffness (mins)	[ ]				☐ No Data	

	I	II	III	IV		
Functional Class (1977)	○	○	○	○	○ No Data	
ESR (@ last visit) (mm/hr)	[ ]				☐ No Data	
CRP (@ last visit) (mg/L)	[ ]				☐ No Data	
Local Lab Range for (mg/L)	[ ]				☐ No Data	
X-ray Erosions	○ no	○ yes			○ No Data	

Fig. 7b

First Visit Form (cont)

Medication Plan for Rheumatoid Arthritis

Name of Medication	Taken Previously	-or-	Taking Currently	Discontinued Today	Continuing or Prescribed Today
Anti-inflammatory	☐		☐	X	☐
Arava	☐		☐	X	☐
Auranolin	☐		☐	X	☐
Azathioprine	☐		☐	X	☐
Chloroquine	☐		☐	X	☐
Cyclophosphamide	☐		☐	X	☐
Enbrel	☐		☐	X	☐
Intramuscular Gold	☐		☐	X	☐
Methotrexate	☐		☐	X	☐
Minocycline	☐		☐	X	☐
Neoral/Cyclosporine	☐		☐	X	☐
Penicillamine	☐		☐	X	☐
Plaquenil	☐		☐	X	☐
Prednisone	☐		☐	X	☐
Remicade	☐		☐	X	☐
Salazopyrine	☐		☐	X	☐
Study/Clinical Trial Drug	☐		☐	X	☐

Fig. 7c